510(k) Summary

APR - 1 2011

510(k) Owner's Name

PreCision Dermatology, Incorporated
400 Highland Corporate Drive
Cumberland, RI 02864
Device Establishment Registration Number: Registration active but number not yet assigned

Contact Individual

Ronald M. Gurge, Ph.D.
Associate Director, Product Research & Development
PreCision Dermatology, Incorporated
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Date Summary Prepared

March 14, 2011

510(k) Device Name

Proprietary Name:	HylatopicPlus™ Cream
Common/Usual Name:	Dressing, Wound & Burn, Hydrogel w/drug and/or biologic
Classification Name:	Dressing, Wound & Burn, Hydrogel w/drug and/or biologic
Panel:	General & Plastic Surgery
CFR Number:	Unclassified
Product code:	MGQ

Devices to Which New Device is Substantially Equivalent

Hylatopic™ Plus Emollient Foam cleared December 7th, 2009 under 510(k) K093051, from Collegium Pharmaceutical, Inc. PreCision Dermatology acquired the legal rights to 510(k) K093051 and thus PreCision has full ownership for the Hylatopic Plus Emollient Foam predicate device.

Device Description

HylatopicPlus Cream is a non-sterile, off-white, low odor, fragrance free, topical product. The HylatopicPlus forms a physical barrier that helps to maintain a moist wound and skin environment. This is a prescription device.

Intended Use of the Device

Under the supervision of a healthcare professional, HylatopicPlus Cream is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. HylatopicPlus Cream also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Device Description and Comparison

A detailed description of the proposed device and its comparison to the predicate device is located in Section 3 of this submission. Both the proposed and referenced predicate devices are oil-in-water emulsions containing humectant and emollient components which donate moisture to the skin and form a semi-permeable physical barrier protecting the skin from exogenous irritants. In the packaging, both the predicate and proposed devices are in the form of a cream. When dispensed, the predicate device forms a foam; during application, the propellant dissipates and the device returns to a cream form as it is spread on the skin. The predicate device is thus a cream form in the packaging and on application to the skin, as is the proposed device. Both the proposed and predicate devices are non-sterile and are applied topically to relieve the symptoms of various dermatoses. A comparison of the intended use and labeling of the proposed and predicate device is located in Section 4 and Appendix 6. All labeling changes consisted of the removal of aerosol specific text and changes to the name and logo of the company marketing the device. PreCision intends to market both the predicate and proposed devices.

Substantial Equivalence

Section 4 of this submission describes the substantial equivalence of the proposed and predicate devices in detail. In summary both devices:

- Have identical indicated uses
- Have identical operating principles
- Are both oil-in-water emulsions that are applied topically
- Contain identical device components at identical quantities
- Have identical shelf-lives
- Are manufactured by identical procedures

Therefore HylatopicPlus Cream is substantially equivalent to the previously cleared Hylatopic™ Plus Emollient Foam.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

PreCision Dermatology, Inc.
% Ronald M. Gurge, Ph.D.
Associate Director, Product Research
and Development
400 Highland Corporate Drive
Cumberland, Rhode Island 02864

APR - 1 2011

Re: K110727
Trade/Device Name: HylatopicPlus™ Cream
Regulatory Class: Unclassified
Product Code: FRO, MGQ
Dated: March 14, 2011
Received: March 16, 2011

Dear Dr. Gurge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K110727

Device Name: HylatopicPlus™ Cream

Indications For Use:

Under the supervision of a healthcare professional, HylatopicPlus Cream is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. HylatopicPlus Cream also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

HylatopicPlus Cream is indicated for use in:

- Atopic Dermatitis
- Allergic Contact Dermatitis
- Radiation Dermatitis

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110727